FDA 510(k) Premarket Notification

# K252888 NeoSculpt Plus

**CLEARED**

Mar 9, 2026
180 days to decision

K252888 · Product code: **PBX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k252888/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Massager, Vacuum, Radio Frequency Induced Heat (PBX) |
| Date received | Sep 10, 2025 |
| Decision date | Mar 9, 2026 |
| Days to decision | 180 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **S&M Medical Co., Ltd.** |
| Location | Gwangju, KR |
| Contact | Young Ok Jo |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Lighten Bridge, LLC** |
| Contact | Edward Park |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k252888/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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